K092986

5. 510(k) Summary of safety and effectiveness

This 510(k) summary of safety and effectiveness information is being submitted in accordance with the requirements of SMDA 1990 and 21 CFR 807.92.

APPLICANT:	Acacia, Inc.
TRADE NAME:	Piston Syringe
COMMON NAME:	Piston Syringe
CLASSIFICATION NAME:	Piston Syringe
DEVICE CLASSIFICATION:	Class II
PRODUCT CODE	FMF
PREDICATE DEVICES:	Baxa Piston Syringe (K951871) Becton Dickinson Safety Syringe (K872820) Sherwood Medical Piston Syringe (K811965) Terumo Hypodermic Syringe (K771205)

OCT 2 7 2009

Substantially Equivalent To:
The Acacia Piston Syringe is substantially equivalent in intended use, principal of operation and technological characteristics to the Baxa Piston Syringe (K951871), Becton Dickinson Safety Syringe (K872820), Sherwood Medical Piston Syringe (K811965), and Terumo Hypodermic Syringe (K771205).

Description of the Device Subject to Premarket Notification:
The Acacia Piston Syringe consists of a calibrated hollow cylindrical body and movable plunger. At the tip of the barrel is a tapered male connector, which can be in a luer lock, luer slip, oral lock, and oral slip configurations.

The Acacia Piston Syringe can also be used as a dispenser without the use of a plunger.

Indications for Use:

The Acacia Piston Syringe is indicated for the injection of fluids into, or withdrawal fluids from, the body. It is also used as a dispenser, a measuring device, and a fluid transfer device.

Technical Characteristics:

The Piston Syringe has similar physical and technical characteristics to the predicate devices.

Performance Data:

All necessary verification and validation testing has been performed for the Piston Syringe to assure substantial equivalence to the predicate devices.

Basis for Determination of Substantial Equivalence:

Upon reviewing the safety and efficacy information provided in this submission and comparing intended use, principle of operation and overall technological characteristics, the Piston Syringe is determined by Acacia, Inc., to be substantially equivalent to the existing legally marketed devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room W-O66-0609
Silver Spring, MD 20993-0002

Acacia, Incorporated
C/O Mr. Mark Job
Responsible Third Party Official
Regulatory Technology Services L.L.C.
1394 25th Street Northwest
Buffalo, Minnesota 55313

OCT 2 7 2009

Re: K092986
Trade/Device Name: Acacia Piston Syringe
Regulation Number: 21 CFR 880.5860
Regulation Name: Piston Syringe
Regulatory Class: II
Product Code: FMF
Dated: October 3, 2009
Received: October 14, 2009

Dear Mr. Job:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/cdrh/mdr/ for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Susan Runner, D.D.S., M.A.
Acting Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K992986

Device Name: Acacia Piston Syringe

Indications for Use:

The Acacia Piston Syringe is indicated for the injection of fluids into, or withdrawal fluids from, the body. It is also used as a dispenser, a measuring device, and a fluid transfer device.

Prescription Use X (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use ____ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Anesthesiology, General Hospital
Infection Control, Dental Devices

510(k) Number: K992986